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MEDICAL DEVICE WARRANTY

DailyCare BioMedical warrants each new device to be free from defects in material and workmanship. This warranty is not transferable. This warranty is effective for a continuous period of one year from initial date of shipment against the original order to the original purchaser. This warranty covers parts, labor, and transportation costs when, upon examination by the

manufacturer, the device is determined to be in fact defective. In order to implement the provisions of warranty repair, the purchaser must notify DailyCare BioMedical concerning suspected defects and then, if so instructed, ship the instrument to the designated facility, correctly packed in an appropriate shipping container, for examination and servicing.

LIMITATIONS AND EXCLUSIONS

This warranty does not cover repairs necessitated by any damage to equipment caused by mishandling, neglect, abuse, customer modification or failure of the user to follow the published operating instructions. Repaired devices are warranted for a period of 30 days and are subject to the limitations and exclusions described in this document. **DailyCare BioMedical reserves the right to make design changes in its products without incurring the obligation to incorporate these changes in products previously delivered.** This warranty applies unless DailyCare BioMedical has agreed to and provided a written exception to this policy.

ATTENTION!

Cardio[24]

- is NOT a diagnostic device. It is only an ECG recorder.
- is NOT a substitute for a traditional ECG diagnosis.
- will NOT tell you if you have heart problems. Only your physician can do that. You should NOT interpret the measurement results yourself.
- is NOT recommended for users with pacemakers.

What you should not do:

- Do NOT operate Cardio[24] at the same time with other electrical devices.
- Do NOT connect Cardio[24] to the PC via USB cable when measuring.
- Do NOT use accessories other than those provided by the manufacturer.
- Do NOT subject the device to water and liquid spillage. Do NOT clean with alcohol, acetones or any other flammable chemical agents.
- Do NOT place the device and its accessories under direct sunlight and harsh environments.
- Do NOT disassemble Cardio[24]. It may cause device malfunction, device failure or damage to the device and you will loose any warranty.

ATTENTION!

Appearance of Irregular Heart Beat indicator

The appearance and flashing of this indicator signifies that ECG irregularities were detected during the 15 second ECG measurement.

NOTE: Please use the device properly by following standard operating procedure. (Please refer to Section 2.2 Page 7) Improper use of the device will cause inaccurate representation of measured results. IHB indicator and/or NOISE indicator may appear if the device is not operated correctly. If you readings are NOT within the reference range, multiple readings are recommended.

As a rule, if you are feeling uncomfortable, regardless of the numbers and symbols on the device, please consult your physicians immediately!

If the Irregular Heart Beat indicator appears more frequently (for example, several times per week on measurements performed daily), or if it suddenly appears more often than usual, please consult your physicians for medical advices.

NOTE: This device is a Lead I Handheld ECG device. The accuracy of this device has been clinically validated. The device does not replace a cardiac examination, but serves to detect Irregular Heart Beats at an early stage.

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INTRODUCTION

1.1 Basic Function of the Heart

The heart has 4 chambers that act together to pump blood throughout the body. The 2 smaller upper chambers are called atria, and the larger lower chambers are called ventricles. The right atrium receives oxygen-depleted blood coming back from the body via 2 large veins: the superior vena cava and inferior vena cava. The right atrium pumps this blood into the right ventricle, which then pumps the blood into the lungs, which is oxygenated. The blood then comes back into the left atrium, which is then pumped into the left ventricle. The left ventricle then pumps the blood back to the circulatory system via the aorta, the largest artery in the body. The pressure that the left ventricle exerts to keep the blood moving throughout the whole body is the blood pressure.

1.2 Conduction System of the Heart

The chambers of the heart pump with the automatic discharge of electricity from the sinoatrial (SA) node, a group of specialized cells in the right atrium. On average, there are 60 to 100 times discharges per minute. When the SA node discharges, both atria contract, and the electrical impulse is relayed to the atrioventricular (AV) node that is between the 2 ventricles. The electrical wave that is propagated at the AV node causes both ventricles to contract and pump blood. The normal delay between the atrium and ventricle contractions is 0.12 to 0.20 seconds. By studying the electrical activity that results when

heart muscle cells contract, we gain insight to the health and workings of the heart. These electrical activities can be detected, recorded and studied with an electrocardiograph, for example Cardio[24].

1.3 What is Cardio[24]

Cardio[24] is a personalized, non-invasive, handheld heart monitoring device designed especially for individual and family use. It is not diagnostic in nature, but only for recording. It allows users to measure and record electrical activities of the heart anywhere and any time. The electrical signals from the heart are obtained by placing thumbs on Cardio[24]'s specially designed conducting plates without using any complicated wires or conducting gel. Cardio[24] takes 30 seconds for each measurement. The device will record 15 seconds of the "Modified ECG signal"[1] and instantly display the average of 3 parameters on the LCD display: the average heart rate (HR), ST segment and QRS interval. These parameters are not the traditional standard ECG readings, but rather, a "Modified Lead I-ECG"[2].

Cardio[24] can transfer all recorded measurements to a personal computer through USB connection for easy viewing, managing and printing of ECG recordings.

---

[1] Cardio[24] uses two conducting electrode plates to measure cardiac activities, unlike traditional ECG device which requires at least 3 electrodes. ECG measured by Cardio[24] is designated as a modified Lead I ECG.

[2] These parameters from Cardio[24] are only for user reference. For interpretation of the parameters, please consult professional physicians. Additional standard 12 lead ECG may need to be performed.

1.4 ECG Variables

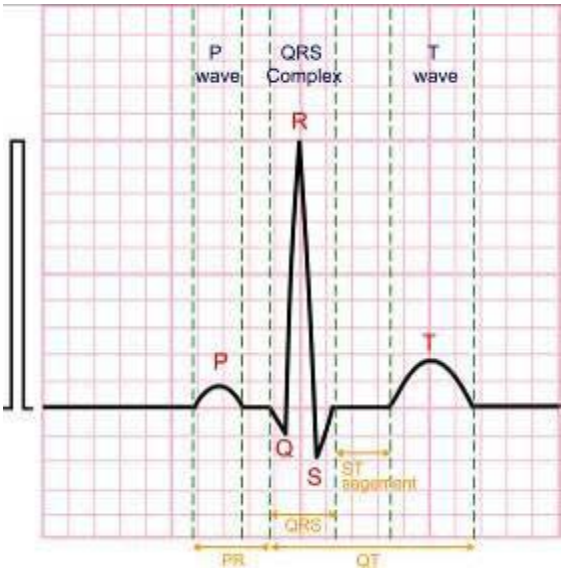


Figure 1. Normal ECG Waveform (Lead I)

Figure 1 is a presentation of a normal ECG waveform from Lead I. Cardio[24] has algorithms that will identify and compute parameters in the table listed below. Table 1 is a list of ECG parameters measured by Cardio[24].

Table 1 Cardio[24] Output Parameters

Parameters	Reference Range
Average Heart Rate (HR)	60 < HR <100 bpm*
ST Segment (ST)	-2 < ST < +2 mm
QRS Interval (QRS)	0.08 s < QRS < 0.12 s
PR Interval	0.12 ~ 0.20 s
QT/QT_c	0.32 ~ 0.44 s / 0 .41 ~ 0.44 s

1.5 Benefits of Cardio[24]

Cardio[24] is a recording device used to monitor the electrical activities of the heart anytime anywhere. It is designed to be small, portable and easy to use. With Cardio[24] you can:

- Take measurements anytime anywhere

  Cardio[24] is available anytime to periodically monitor the heart throughout the day.

- Manage ECG recordings over time

  Cardio[24] software allows users to manage their ECG recording to monitor ECG changes over time.

- Provide your physicians with these historic data

  Data generated by Cardio[24] can be used as a reference when diagnosing for conditions in the future.

1.6 Common Causes of Abnormal ECG Tracings

Individuals with high risk factors might have abnormal ECG tracings. These include people who smoke, who have high cholesterol, who are over weighted or who have a family history of heart complications. Please consult your physician if you are concerned about your ECG recording and symptoms to get more information about your condition.

PRODUCT DESCRIPTION

2.1 Product Design

2.1.1 Product Package

Standard Package:

☑	Cardio24	x 1
☑	USB Cable	x 1
☑	Cardio24 Software CD	x 1
☑	Cardio24 User's Manual	x 1

Optional Accessories:

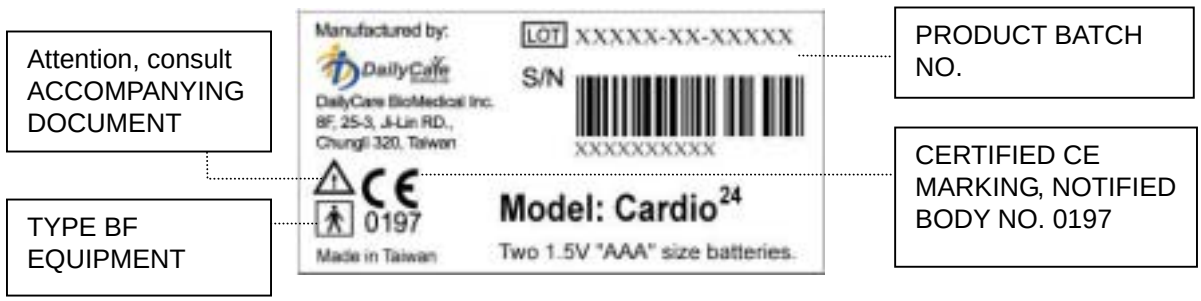
☑	Auxiliary Electrode Cable	x 1

Not Included:

1) Electrode gel pad. These pads can be purchased at local drug stores.

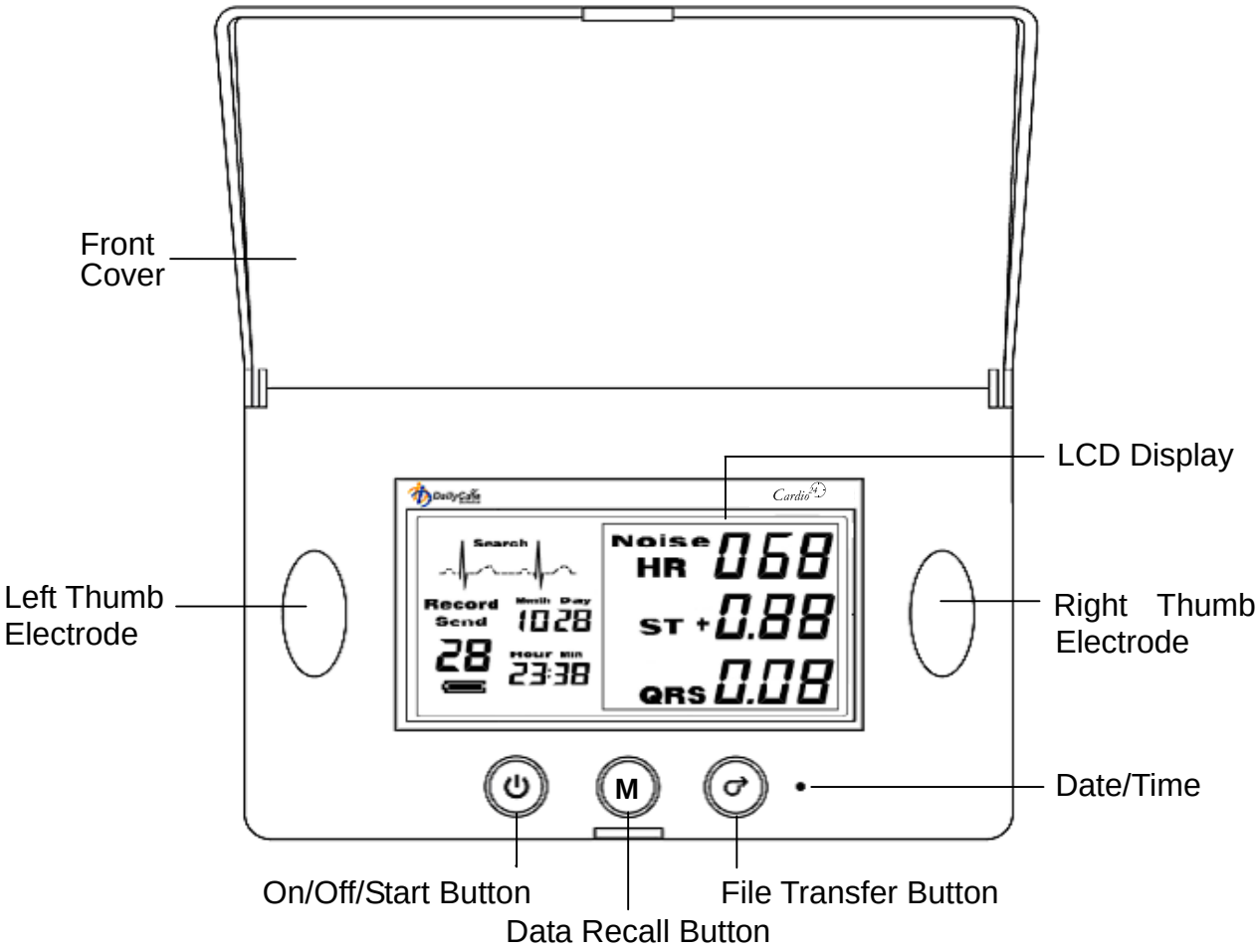
2) AAA alkaline battery. Cardio24 needs two to operate.

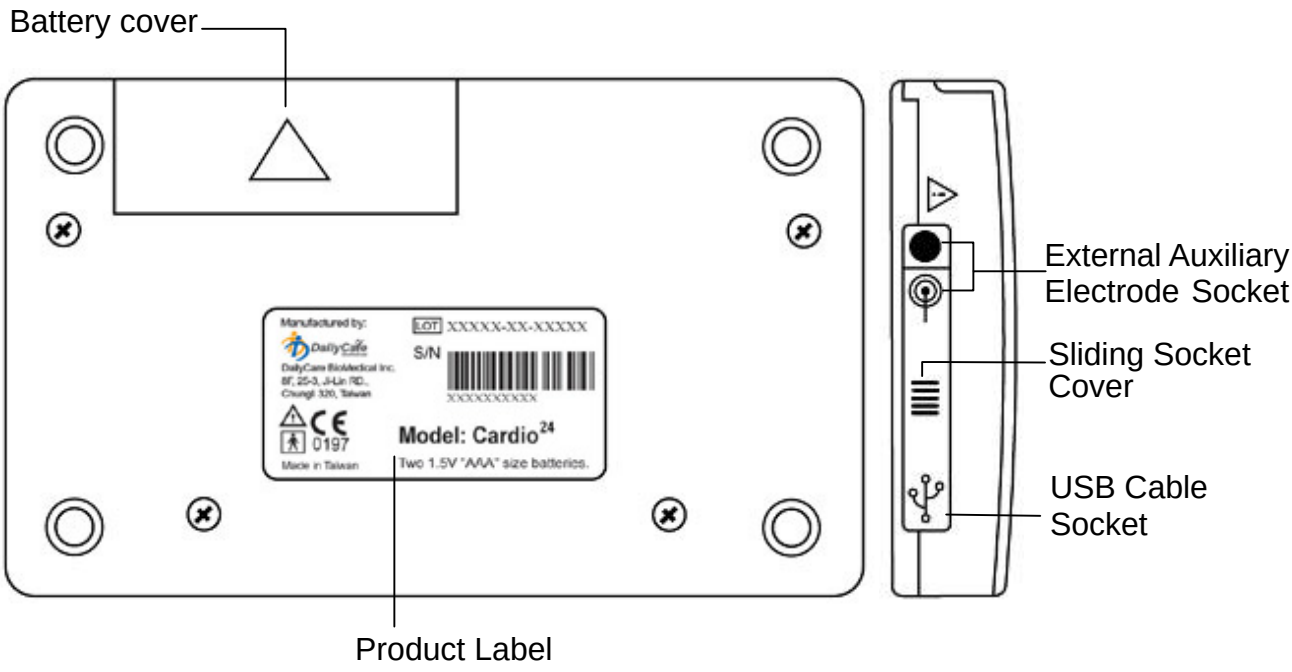
2.1.2 Product Label



Cardio24 IS TYPE B EQUIPMENT WITH F-TYPE APPLIED PART IN EN IEC60601-1 STANDARD

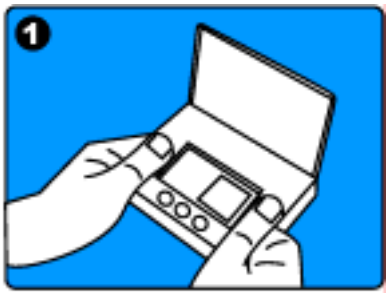
2.1.3 Exterior Design



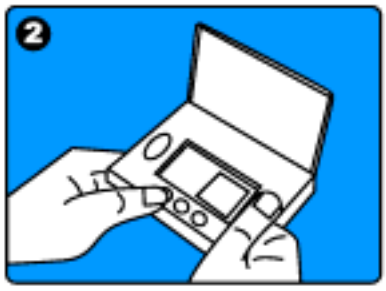


2.2 Operating Cardio^{24}

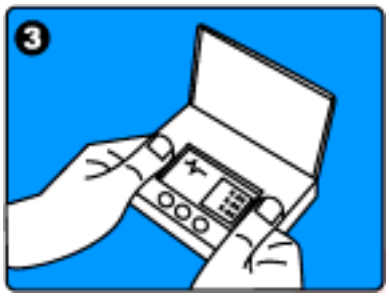
2.2.1 Procedure



Open the cover of Cardio^{24}.



Press ⏻ once to start measuring. (Allow 30 seconds)

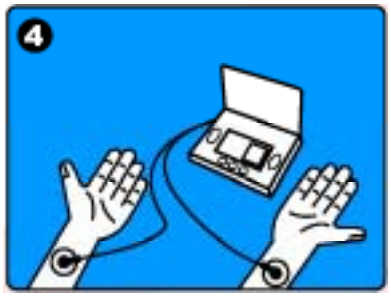


LCD screen will display the parameters after measurement.

Steps	Descriptions
1	**Wash and dry** your hands before use.
2	**Sit down** and place your hands comfortably on a table or on your laps. Hold Cardio^{24} in your hands steadily. Calm and relax yourself with regular breathing.
3	**Press ⏻ once** and **place right and left thumbs gently on the conduction electrodes** to start measurement. - During measurement, a timer will be displayed at the right bottom corner of LCD screen. - During the 30 seconds of measurement, **avoid talking and keep a steady but gentle contact** of the thumbs to the conduction electrodes. - Cardio^{24} can store up to a maximum of 30 data files. Memory will be cleared automatically if more than 30 data files are stored. - Three parameters of the measured results will be displayed on the LCD screen. To start another measurement, simply press ⏻ again. **Please note that Cardio^{24} cannot be powered off during recording.**
4	**Hold ⏻ for 3 seconds to power off the device**. Cardio^{24} will be powered off automatically if left idle for more than 2 minutes to save power.

(Optional Method)

Cardio[24] has optional auxiliary electrodes as an alternative way for users to take ECG readings. Please follow the steps below when using the auxiliary electrodes:

Steps	Descriptions
1	Place the sticky electrode pad (not included) on the middle of the inner forearms. **(Users can buy qualified electrode pads from any medical device stores.)**
2	Slide the socket cover to expose the optional electrode socket and connect the cable to Cardio[24] accordingly. Please connect the RED electrode on the right arm and the BLUE electrode on the left arm as shown on the right. 
3	Start the measurement as described above. (Section 2.2.1)

The auxiliary electrode socket is located on the left of the device.

Both auxiliary electrode and USB sockets on the device are only to be used with the standard accessories provided. Warranty will NOT cover damages that result from NOT complying with the instructions.

2.2.2 Control Buttons

Control Button Descriptions

Buttons	Descriptions
(Button 1)	**Power On/ Start Measurement/Power Off** ~Press once to power on and start measurement. ~Hold for 3 seconds to power off. ~After measuring, press again to start another measurement.
(Button 2)	**Data Recall** ~Press once to enter data recall mode. The latest data recorded will be displayed. ~Press again to recall other recorded data, starting from the first. ~Hold for 3 seconds, or press any other button, to leave data recall mode.
(Button 3)	**Data Transfer/Data Clearance** ~Connect Cardio24 to PC with USB cable and press once to start transferring of stored data. ~When the device is on, hold button for 3 seconds to manually clear all stored data.
• (Hidden Button)	**Time Setting** ~When the device is on, press once to set the right time. ~Press Button 2 (M) to select month/date/time. ~Press Button 3 to adjust value.

2.2.3 LCD Display

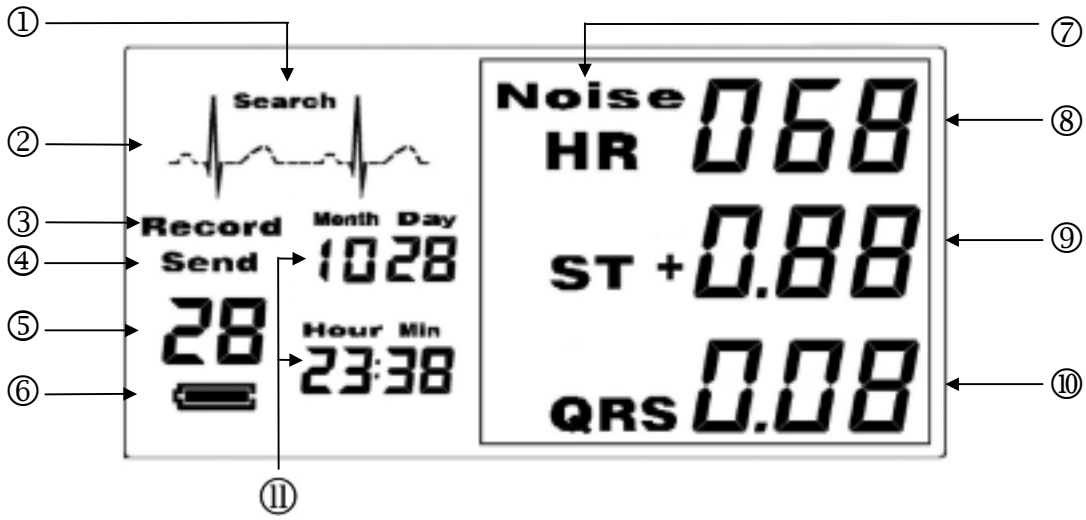


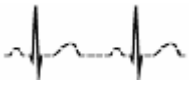
Figure 2. LCD Display Panel

Reference Range of Measured Results

	Reference Range	Warning Sign
HR	60 < HR＜100 bpm	Flash
ST	-2 < ST＜+2 mm	Flash
QRS	0.08 < QRS＜0.12 sec	Flash

Attention: The information above is for reference ONLY. In case Irregular Heart Beats are detected, measurement made with this device should only be evaluated after consulting a doctor. If the measured parameters fall within the reference range and NO Irregular Heart Beats are detected and the user still feels any discomforts, please consult an appropriate physician. Measured data by Cardio24 may be provided for a physician for reference and further analysis.

2.2.4 LCD Display Description

#	Item	Descriptions
①	**Search**	Displays when Cardio^{24} is searching for signals. (Takes around 3~5 seconds)
②		**Flashes** right after measurement when Irregular Heart Beats are detected. **Note:** Please consult your physician if Irregular Heart Beats are detected on a regular basis.
③	**Record**	Displays when Cardio^{24} is in data recall mode.
④	**Send**	Displays when Cardio^{24} is transferring data.
⑤	Total Number/ Data File Number	During power on mode, the number represents the total number of data files recorded. In data recall mode, the number represents the serial number of data file being displayed.
⑥	Battery Condition	indicates the battery is normal. indicates the battery is low.
⑦	**Noise**	**Noise** is displayed after measurement when noisy signals are detected more than 5 times during measurement. PLEASE MEASURE AGAIN. Note: Under above conditions, parameters displayed on LCD may not be accurate but will still be stored in the device.
⑧	HR	Average Heart Rate of 15 seconds. **Flashes** right after measurement when the numbers are out of reference range.
⑨	ST	ST segment. **Flashes** right after measurement when the numbers are out of reference range.
⑩	QRS	QRS interval. **Flashes** right after measurement when the numbers are out of reference range.
⑪	Date/Time	Month/Day/Hour/Minute

2.3 Product Specifications

Input impedance	> 10 M - Ohm
Input dynamic range	+/- 2 mV
Bandwidth	0.15 – 40 Hz
CMRR (Common Mode Rejection Ration)	> 60 db
A/D conversion	12 bit
Sampling frequency	250 samples/sec
Measurement Time	~30 seconds (First 10 seconds is to search for signals)
Display	LCD display panel
Input	Dry conduction electrodes and/or external auxiliary electrodes
Output	USB interface
Power Supply	1.5V (AAA) X 2
Size	12 X 8 X 2 cm
Weight	134 g (Not including batteries)
Environmental Conditions:	
Storage temperature	-4°F ~122°F (-20°C~ 50°C)
Operating temperature	50°F ~104°F (10°C ~ 40°C)
Humidity	25% ~ 95%
Measurement Range:	
Average heart rate	45 to 180 bpm
ST segment	-3 to +3 mm
QRS interval	< 0.20 sec

Cardio24 SOFTWARE

3.1 System Requirements

Operating System: Windows 98/98SE/2000/XP

Hardware Requirements:

- CPU: Pentium III and above
- Memory: 100MB and above
- Hard Disk capacity: 100MB and above
- Data transmission media: Universal Serial Bus (USB)
- DPI of Screen: 1024 x 768

3.2 Installation

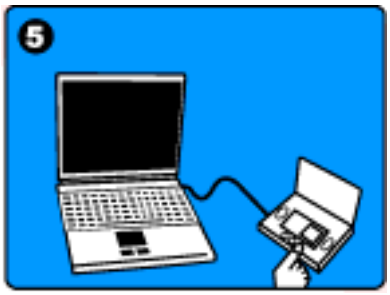
Figure 3. Cardio24 Software Main Page

Insert Cardio24 software CD into the CD-ROM. Select “Software Installation” from the main page and setup will run automatically. If

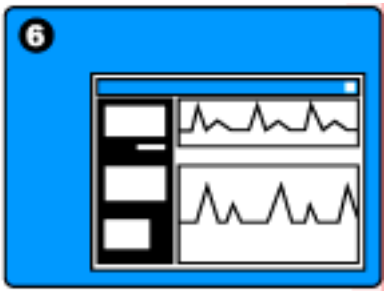
auto-installation does not start, double click on the “autorun.exe” application file in the CD to install manually. Follow the Setup Wizard instruction on the screen.

3.3 File Transfer

Overview of File Transfer



1. Cardio24 uses USB cable to connect to PC.



2. After pressing , content of data files will be transferred and displayed on the monitor.

All data files recorded in Cardio24 can be transferred to PC for analysis through the USB port on the left side of Cardio24 shown in Figure 4.

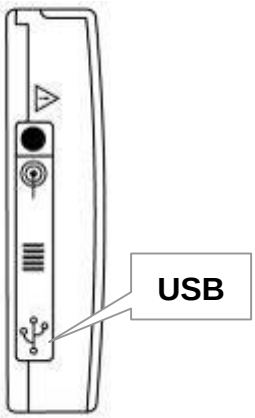


Figure 4. Cardio24 USB port

Steps for file transfer. Please follow the following steps:

1. Start Cardio24 software by clicking on the Cardio24 icon
   A “Disconnected” status will be shown on the bottom left of the main menu (Figure 5).

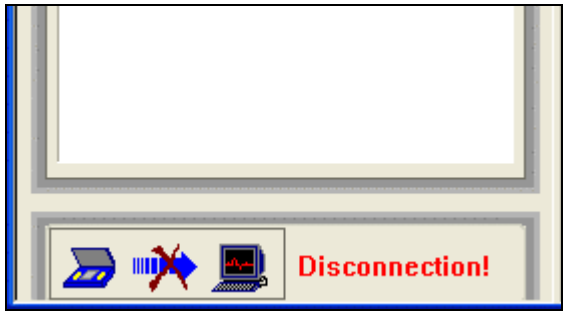


Figure 5. ECG not connected to PC

2. Slide the socket cover to expose the USB port on Cardio24 (Figure 6). Locate available USB port of computer. Connect Cardio24 as shown below at point “A” to PC at point “B” using the USB cable provided.

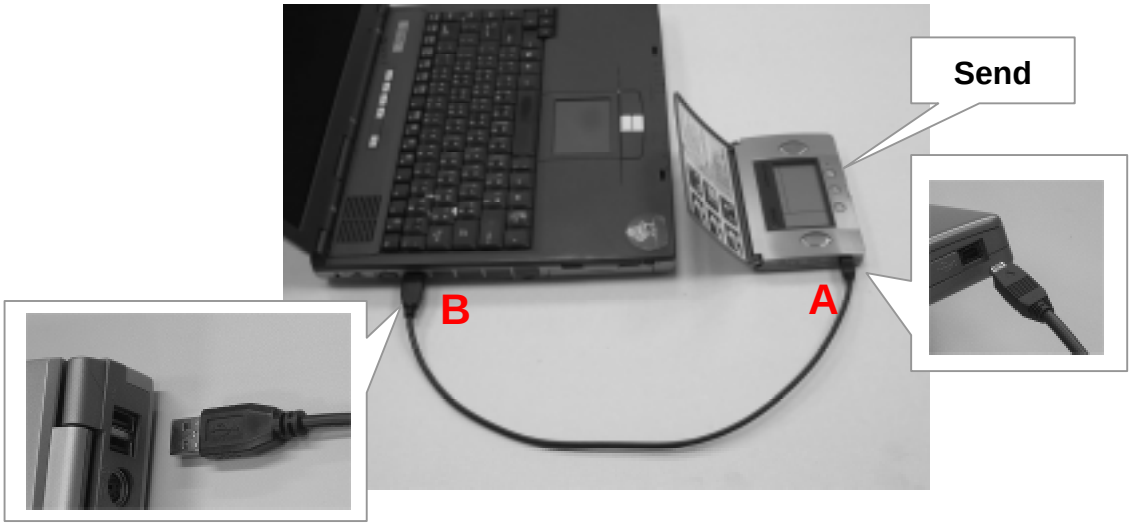


Figure 6. Connection of USB Cable

3. A “Connected” status will be shown as in Figure 7.

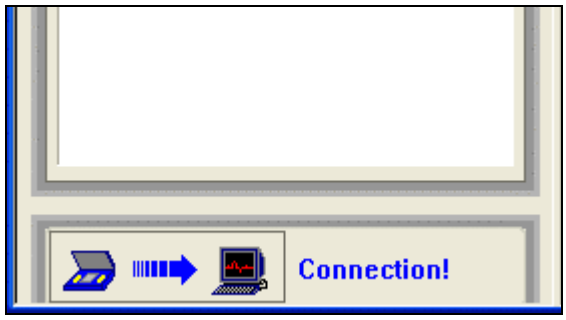


Figure 7. ECG connected to PC

4. Press ⏻ on Cardio24 and **Send** will appear on the LCD display, indicating a transfer of the data files to the PC. The number below **Send** is the serial number of the data files currently downloading to the PC. A transmission window will appear on the PC to show data transmission in progress as shown below.

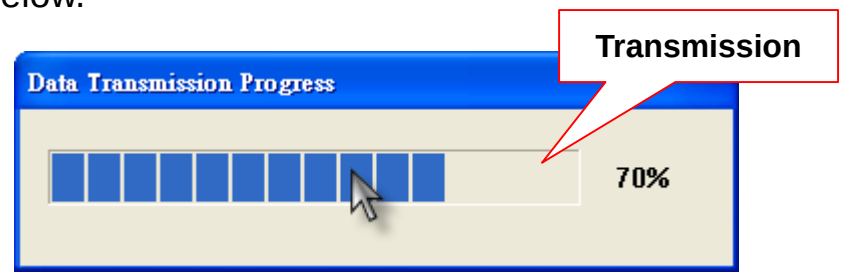


Figure 8. Data Transmission Progress Window

- **Cardio24 will automatically erase the memory after data files have been transferred to the PC successfully.**
- If **Send** flashes after pressing ⏻ or during file transfer, it means that the connection between Cardio24 and PC has failed. Please close and start the software again, or reconnect the USB cable.
- If number 0 appears below **Send** after pressing ⏻, it indicates that there are no more data files in Cardio24. File transfer is not needed.

3.4 Software Interface

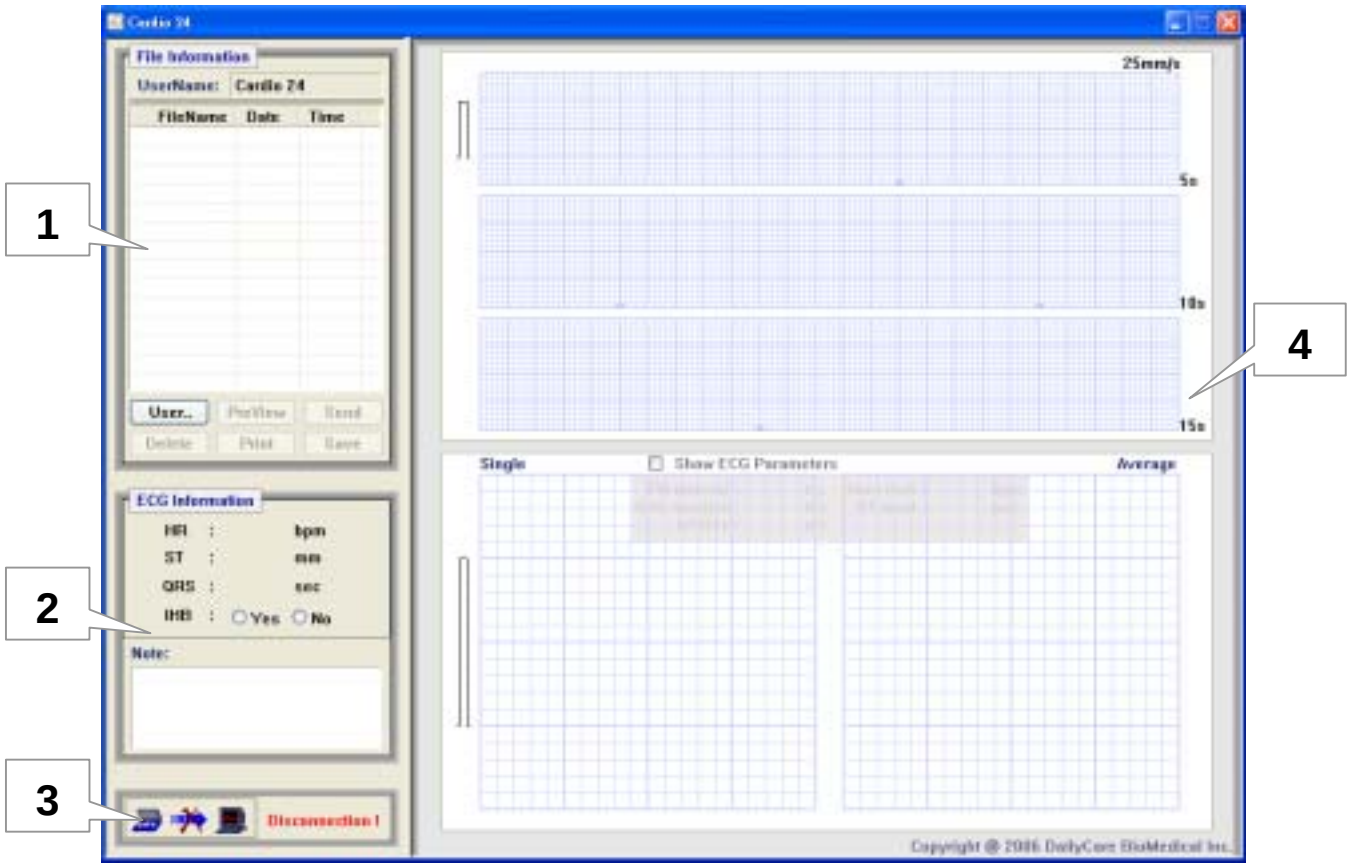


Figure 9. Cardio[24] Database Software Interface Details

Cardio[24] has a simple analysis interface as shown in Figure 9. This analysis and database management system is divided into four main parts:

(1) User and file management;

(2) Average ECG parameters display and remarks;

(3) Connection status of ECG to PC;

(4) ECG record (15 seconds) and diagram analysis display.

3.5 User Management

Under “File information”, two rows of function keys are located at the bottom for managing user names and user ECG files as shown in Figure 10.

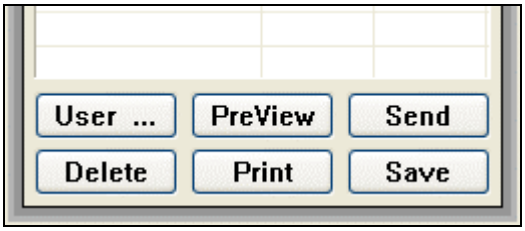


Figure 10. Function keys

The function keys are described as follows:

Function Keys	Description
User ...	Add, Delete or Change User
PreView	Preview File for Printing
Send	Send Selected Files
Delete	Delete Files from Record
Print	Print Selected Files
Save	Save ECG Figures

Detailed descriptions of Function Keys are as follows:

3.5.1 Add a new User

1. Click on [User..] function key under File Management. The user Management Window will appear as shown in Figure 11.

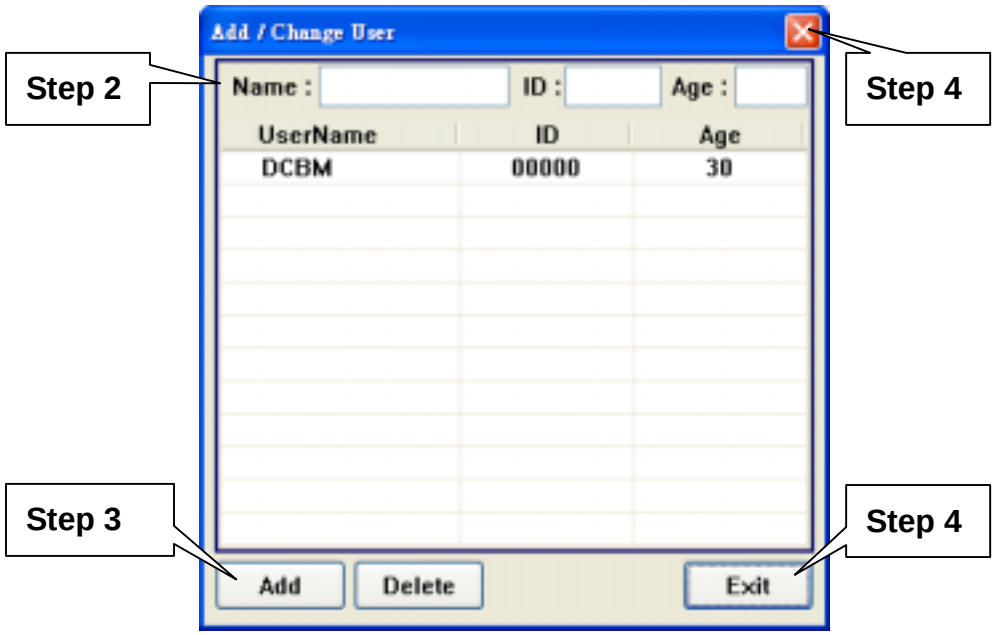


Figure 11. User Management Window

2. Enter user name, ID, and Age.

3. Click on [Add] and a new user will be added to the table. Use only characters and numbers for user name. If the user name is entered inappropriately, a warning window will appear as shown.

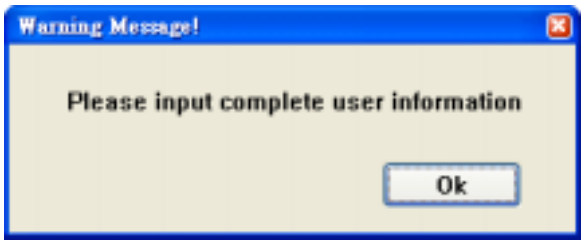


Figure 12. User Information Incomplete Window

4. Repeat step 2 and 3 to add more new users.

5. Click on [Exit] or [X] to close the user management window.

3.5.2 Delete a User

1. Click on [User..] function key under “File Management”.
2. Select the user to be deleted by clicking on the name.
3. Select [Delete]. A warning window will appear as shown below.

Figure 13. Steps to Delete User

4. Select [Yes] to delete. Select [No] to cancel the deletion.
5. Click on [Exit] or close the window to exit.

3.5.3 Change a User

Select a user by clicking on the user name. Then close the window to return to main page. Alternatively, double-clicking on the user window will select the user and close the window automatically.

3.6 File Management

This section will show users how to manage their files with the menu under "File Information". At least one file has to be selected to use the following functions: PreView, Send, Delete, Print or Save. Users can select one or more files by clicking on the box on the left of the file.

3.6.1 File Preview and Print

1. Select one or more files to preview by clicking on the box to the left of the file name. A check sign "√ " will appear as shown in Figure 14.

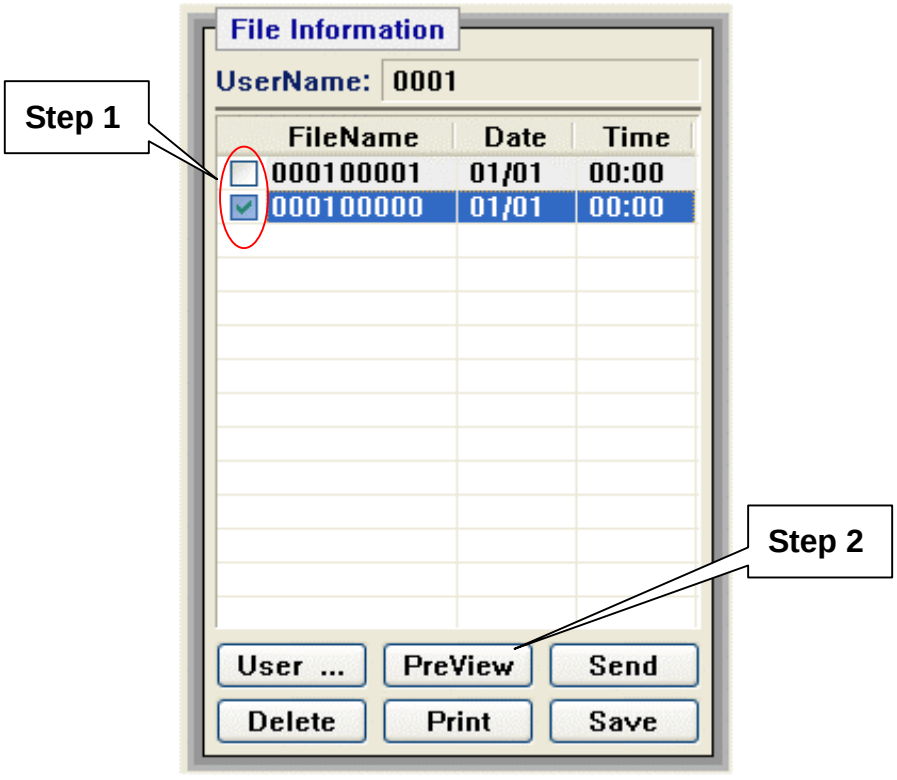


Figure 14. Steps to Preview Files

2. Select Preview and a preview window will appear as shown.

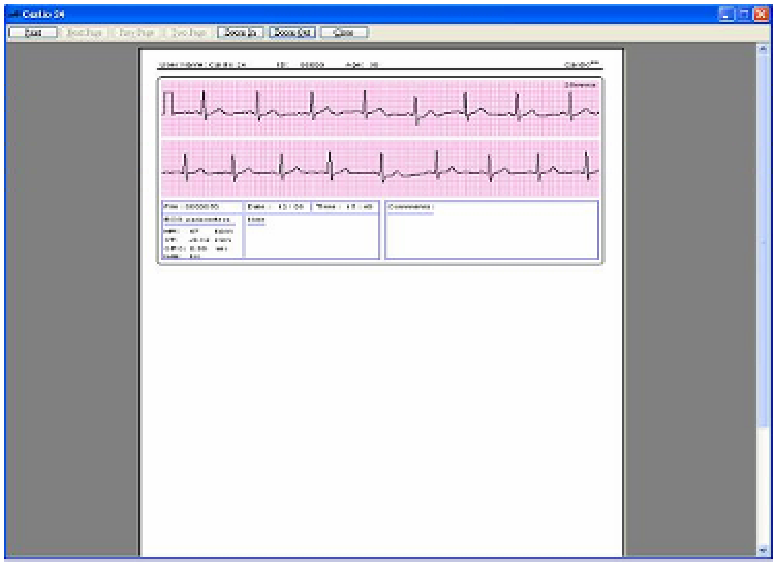


Figure 15. Preview ECG Pattern Parameter for Printout

There are 6 function keys in the preview window:

Select Zoom In to enlarge pattern diagram.

Select Zoom Out to reduce pattern diagram.

Select Page up to page up.

Select Page down to page down.

Select Print to print.

Select Close to exit preview window and return to the main page.

3.6.2 Send Files

1. Under “File Management”, select the files by clicking on the box beside the file name. A check sign “√ ” will appear as shown in Figure 16.

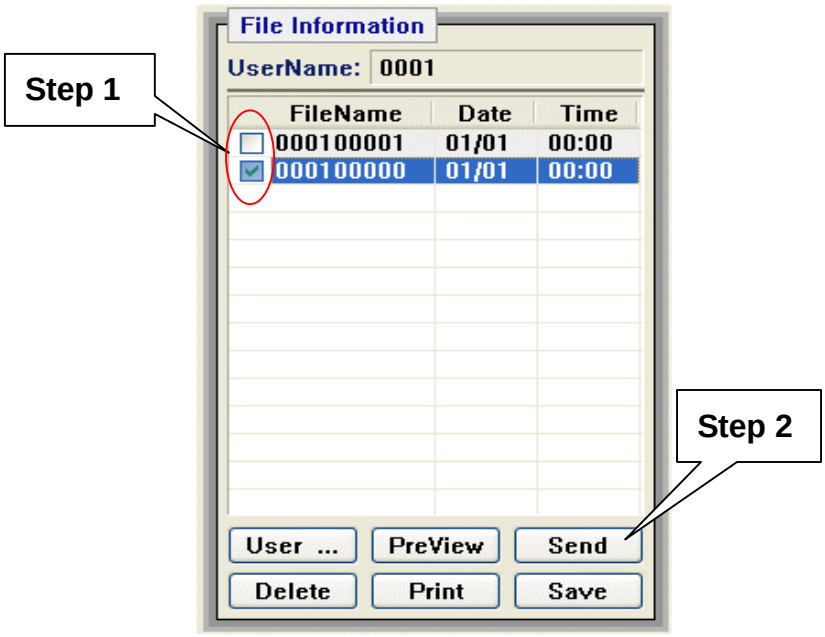


Figure 16. Select Files to Send

2. Select Send and a Send Window will appear as shown below in Figure 17.

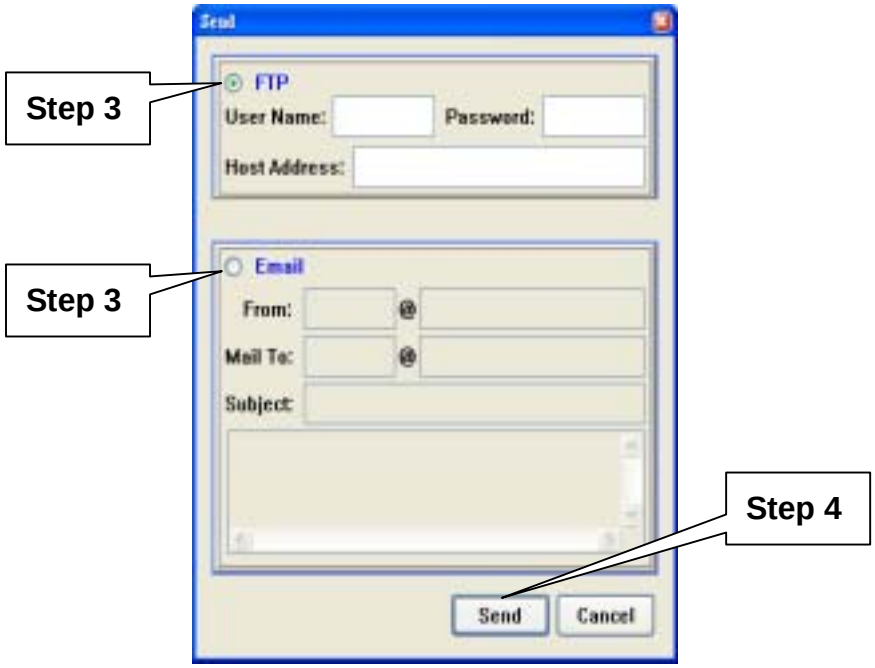


Figure 17. Select Sending Method

There are 2 options available:

a. Select FTP by clicking on the circle to the left. The other option will be grayed out. Type in User Name, Password, and Host address. (Refer to Figure 17) These files will be the original ECG data files. If an error is made, a Warning Window will appear as shown below.

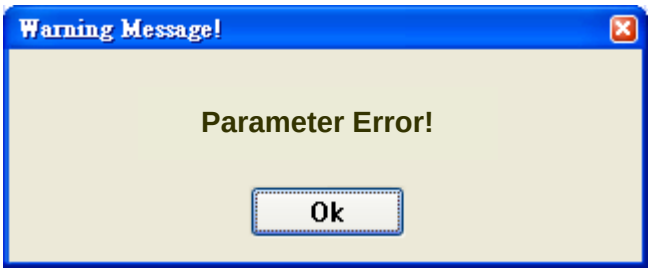


Figure 18. FTP Error Warning Window

b. Select Email by clicking on the circle to the left. Type in email address of Sender (From), Receiver (To), Subject and Body Text (Refer to Figure 17) to send files through email. User must use an email account and server set up with Microsoft Outlook or Outlook Express. These files will be converted to .BMP format and sent to the receiver. If an error is made, a warning window will appear as shown below.

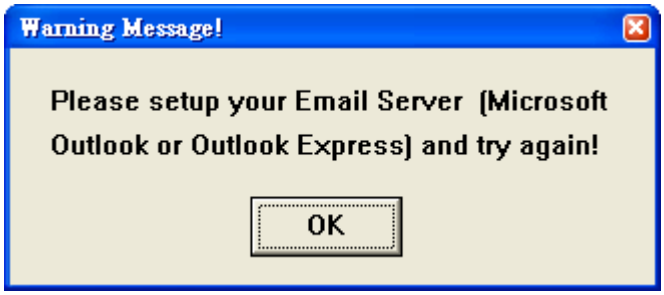


Figure 19. Email Account Error Warning Window

3. Click on Send. Repeat the above steps to send another file. Note that you can send multiple files at one time.

3.6.3 Delete Files

1. Under “File Management”, select the files by clicking on the box beside the file name. A check sign “√ ” will appear as shown below.

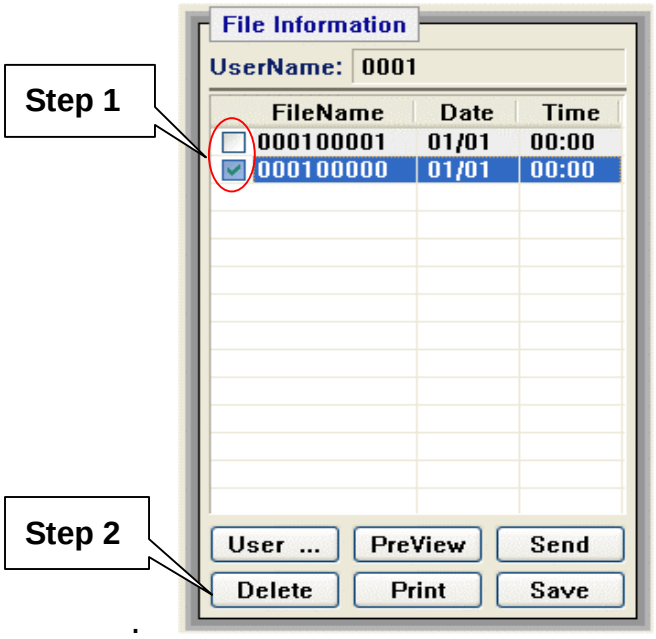


Figure 20. Steps to Delete Files

2. Select Delete and a confirmation warning window will appear as shown.

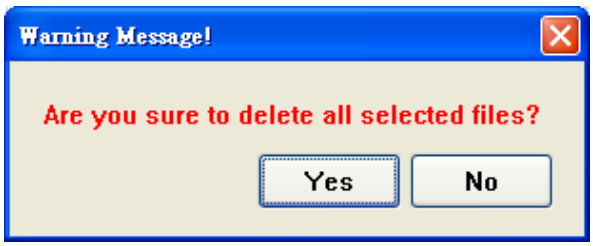


Figure 21. Confirm Deletion of Selected Files

3. Select Yes to delete the checked files. Window will close automatically. Select No to cancel the deletion.

4. Users can repeat above steps to select more files for deletion. Click again to deselect the files.

3.6.4 Print Files

1. Click the box beside the file(s) to print. More than one file can be selected to be printed at one time. (Figure 22)

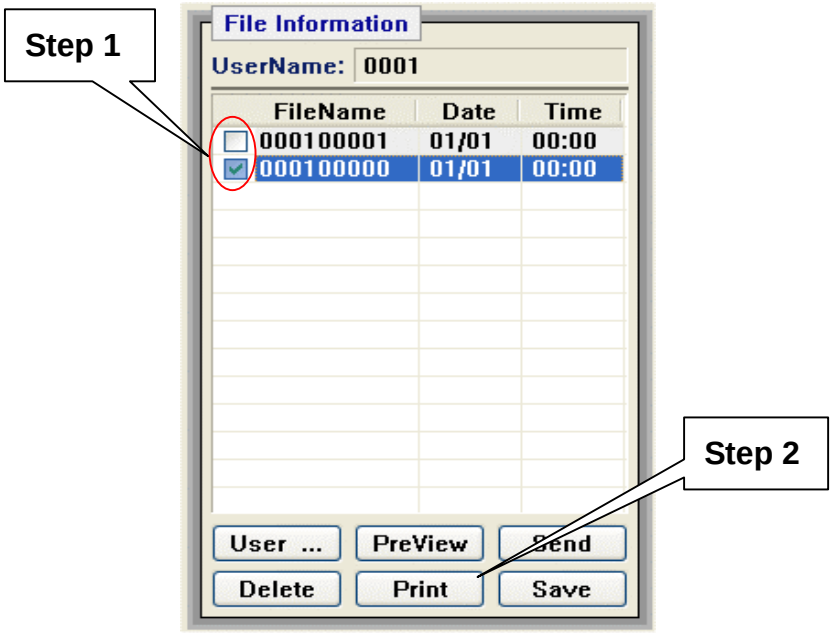


Figure 22. Steps to Print Selected Files

2. Select Print and printer selection window will appear.

3. Choose printer and print options accordingly. After printing, the window will close and return to the main page.

3.6.5 Save Files

1. Click the box beside the file(s) to save. More than one file can be selected to be saved at one time. (Figure 23)

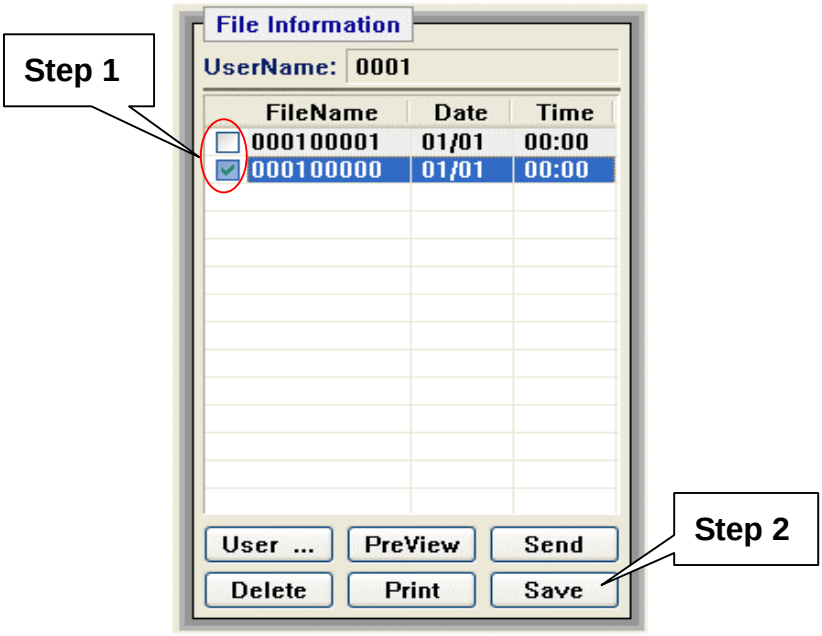


Figure 23. Steps to Save Selected Files

2. Select Save There are 2 options(Figure 24)

- Save to "Default directory". Click on the button to the left. Selected files will be saved in .BMP format at the default path. Any compatible image program can be used to open and edit .BMP files.
- Save to "Followed directory" where the user can specify the specific folder in which to save files.

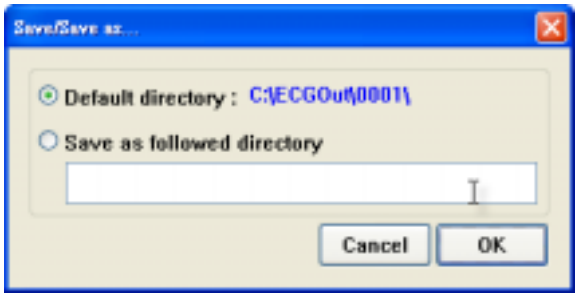


Figure 24. Save ECG File

3.6.6 File Review and Remarks

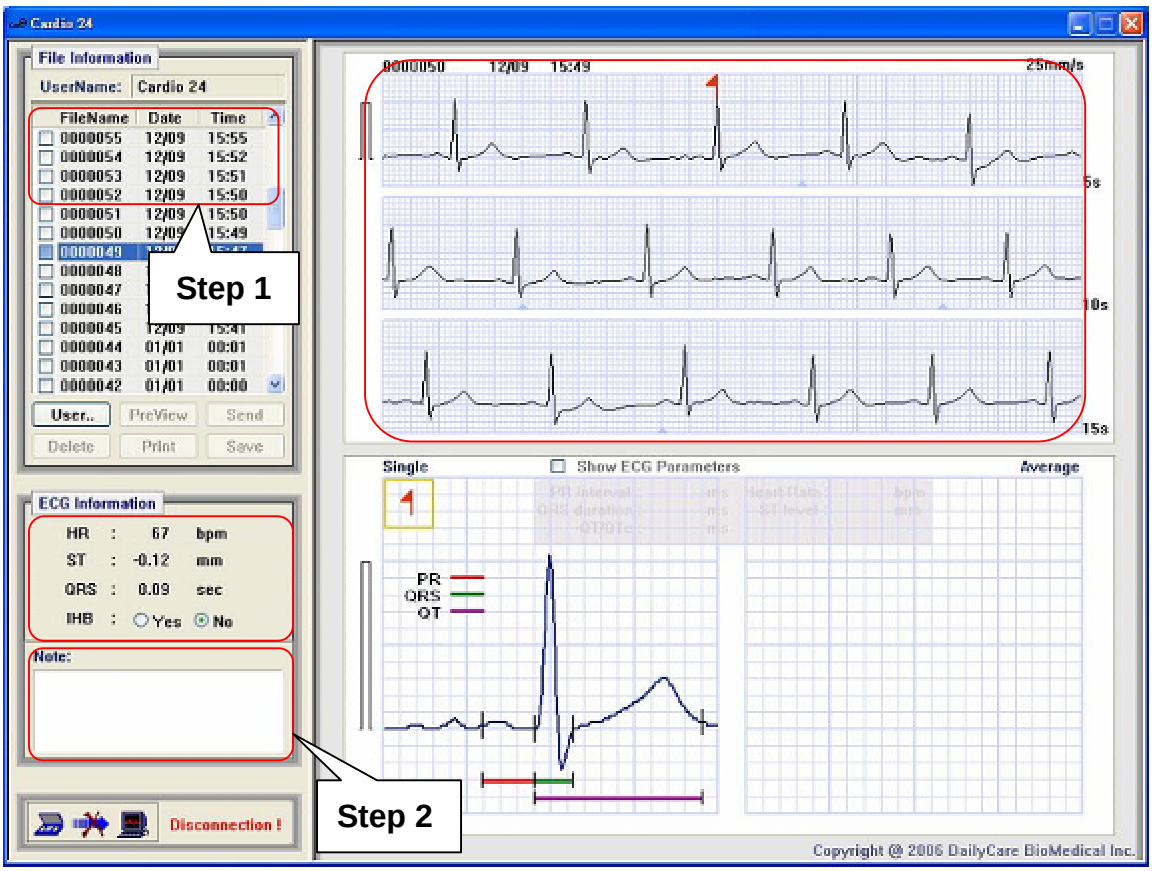


Figure 25. Review ECG Parameters File

1. Click once on the file listed under “File Management”. The file selected will be highlighted in blue with its 15 seconds of recording displayed on the right. (Figure 25)

- Only one file can be selected for review at one time. The ECG recordings window is separated into an upper and a lower section. The upper section shows 15 continuous seconds of ECG signals. The lower section is separated into two sides. The left side shows a single ECG signal. The right side shows an average ECG signal.

2. Users can enter or edit notes under the “Notes” section as shown in Figure 25. The notes will be saved automatically.

DATA ANALYSIS

4.1 Single ECG Signal and Parameters

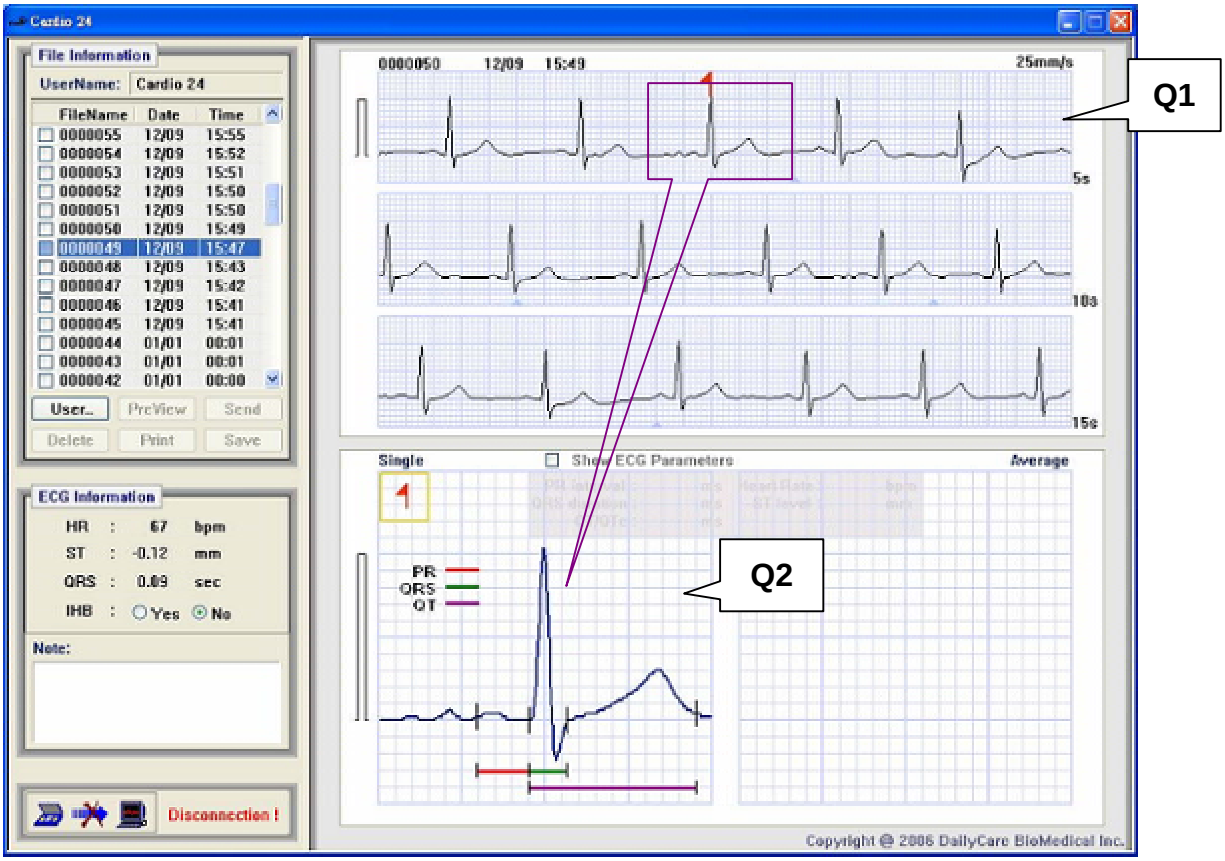


Figure 26. 15 Seconds signal recording with Single signal display

1. Start up the Cardio[24] software by clicking on the icon .

2. Select a “User” under “File Management”. Then select a file to view by clicking on it.

3. A 15-second recording will be shown on the right side of the screen in quadrant 1, Q1. (Figure 26)

4. Click on the “ECG Parameter Square” as shown in Figure 27. This will display the ECG Parameter of the signal with the red flag on top of it. The display area would point to the left as shown with the circle. Click on the square again to parameter values. (Figure 28)

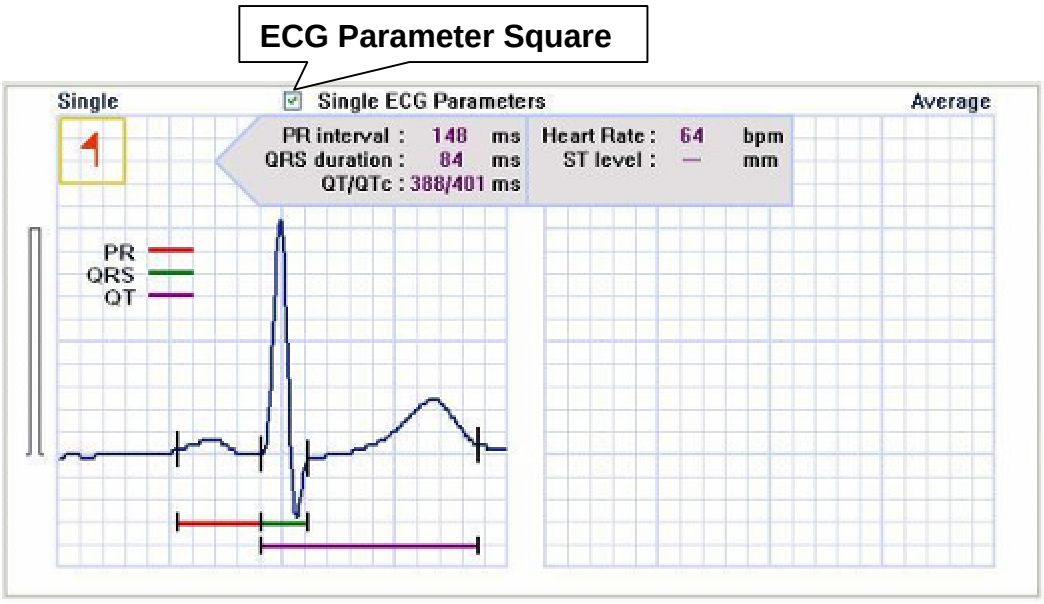


Figure 27. Single ECG parameters

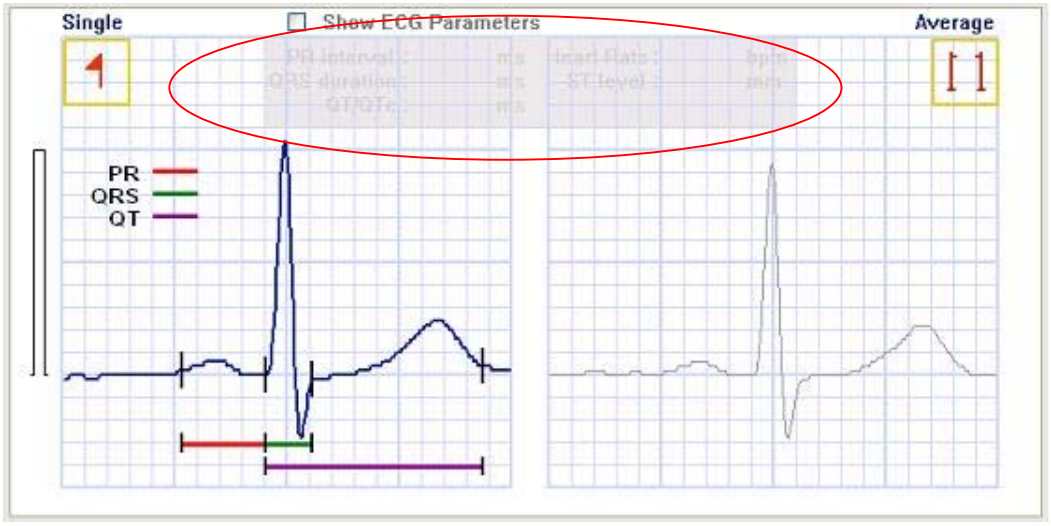


Figure 28. Hide ECG Parameters

5. Move the red flag in quadrant 1, Q1, by clicking on any QRS complex. The selected signal will be displayed in quadrant 2, Q2, with its signal parameters.
    - Single ECG parameters include PR interval, QRS duration, QT/QT_c and heart rate.

4.2 Average ECG Signals and Parameters

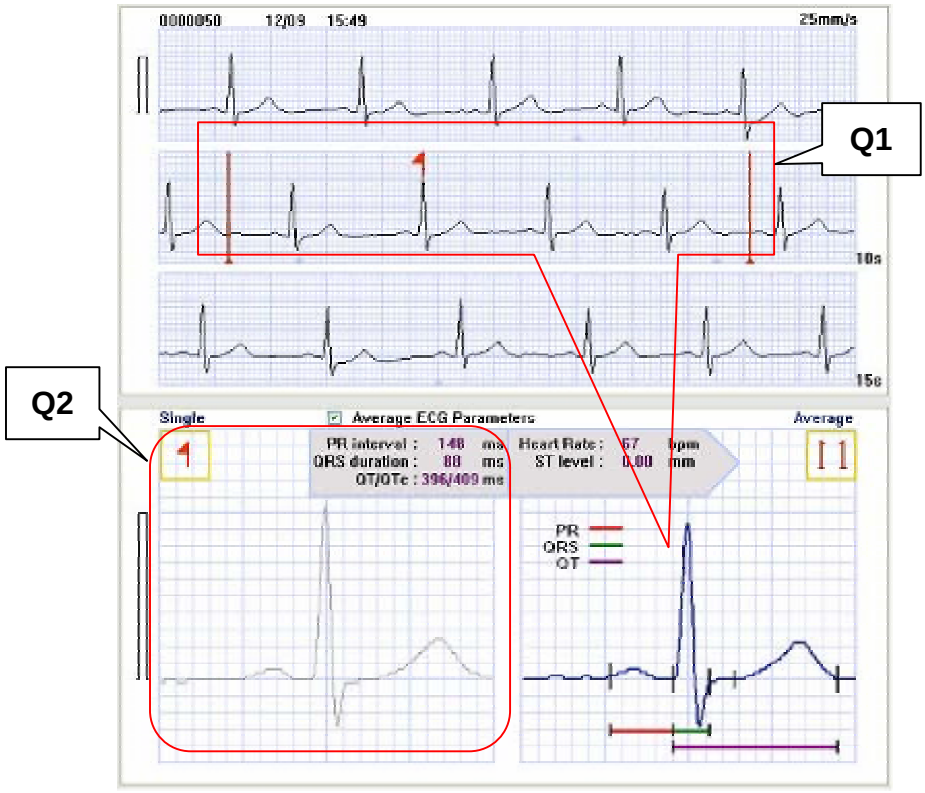


Figure 29. 15-second signal recording with average ECG Parameters

1. Start up the Cardio24 software by clicking on the icon .
2. Select a “User” under “File Management”. Then select a file to view by clicking on it.
3. A 15-second recording will be shown on the right side of the screen in quadrant 1, Q1, with a red flag in the yellow square in quadrant 2, Q2. (Figure 29)
4. Click on the “ECG Parameter Square”. This will display the ECG Parameter of the ECG signal with the red flag on top of it.
5. To select a range, right click once on the graph to mark the beginning of a range and right click again on the graph to mark the end of the range as shown in Figure 29. Red bars denote the range selected.
   - As a range is selected, the display area will point to the right as shown in the red circle in Figure 30. This denotes that the

parameters shown are averages calculated from the range chosen.

- Users can switch between single or average views by clicking on the area in Quadrant 2, Q2, or Quadrant 3, Q3.

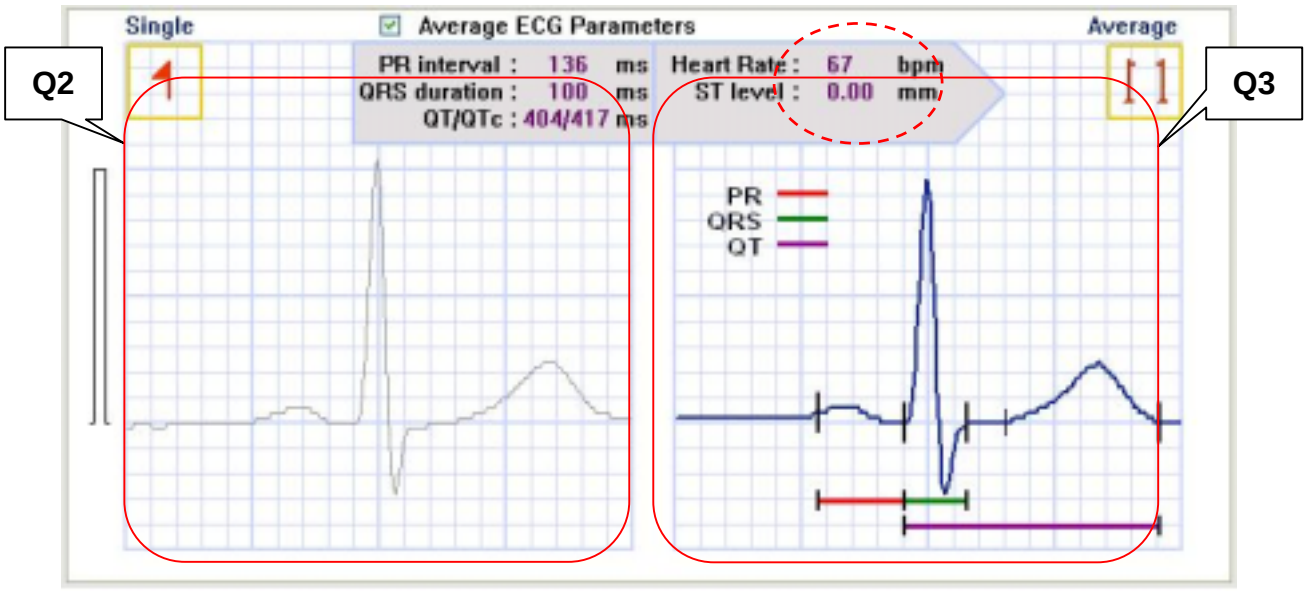


Figure 30. Average ECG Signal and Parameters

4.3 Understanding ECG Parameters

4.3.1 Reading the Graph (Figure 31)

The Y-axis represents voltage in mV. The bar indicated below represents 1millivolt (mV). This denotes the electrical strength of the signal. Therefore, each big square represent 0.5 mV and each small square represent 0.1mV.

The X-axis represents time in seconds. Each big square represent 0.2 seconds. Therefore, each small square represents 0.04 seconds.

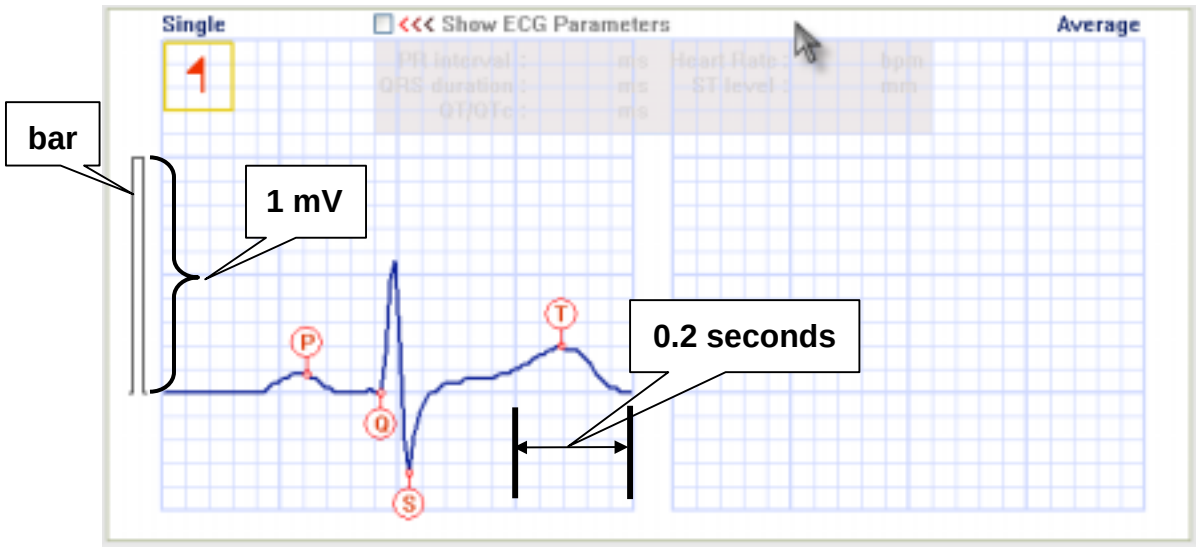


Figure 31. ECG graph

4.3.2 ECG Waves and Parameters

The following is a summary of the ECG wave morphologies and parameters that users can use as a guide to interpret their ECG recordings. For more technical information, please refer to the reference section.

- **P wave:** The P wave results from atria contraction. P wave is generally about 1 box wide or 1 box tall. P wave that exceeds these might indicate atria hypertrophy, i.e., enlargement.
- **PR Interval**: The PR interval is measured from the start of the P wave to the start of Q wave. It represents the duration of **atria depolarization**. Normal duration is from **0.12 to 0.20 seconds.** If the PR interval is greater than 0.20 seconds, then an AV block might be present.
- **QRS Duration**: The QRS duration is measured from the start of Q wave to the end of S wave. It represents the

duration of **ventricle depolarization**. Normal duration is from **0.08 ~ 0.12 seconds**. If duration is longer, it might indicate presence of bundle branch blocks or WPW.

- **QT/QT_c**: The Q T/QT_c is measured from the start of the Q wave to the end of T wave. QT interval represents the duration of **activation and recovery of the ventricular muscle**. This duration varies inversely with the heart rate. The normal QT_c is approximately **0.41** seconds or an accurate measurement, it is corrected with the heart rate with the following formula to get QT_c:

  $$QT_c = QT + 1.75 (HR – 60)$$

- **ST Segment**: The ST segment is measured from end of S wave, J point, to the start of T wave. This segment is important in identifying pathology such as myocardial infarctions (elevations) and ischemia (depressions).

To learn more about the analysis of ECG parameters, please refer to the list of references provided in the Reference Section.

4.4 Redefining ECG Waves

This section is highly recommended for doctors only. The power of the device lies in the algorithm which identifies and defines P, Q, R, S and T wave intervals to generate the parameters observed on the file. The algorithm is highly precise and accurate which is observed in a correlation study with standard ECG device.

In order to present a flexible format, the software is developed with the ability to redefine the waves. This should only be done by a medical professional who has great experience with ECG analysis and interpretation. Therefore, users are strongly advised against performing the function in this section unless under the guidance of a medical professional.

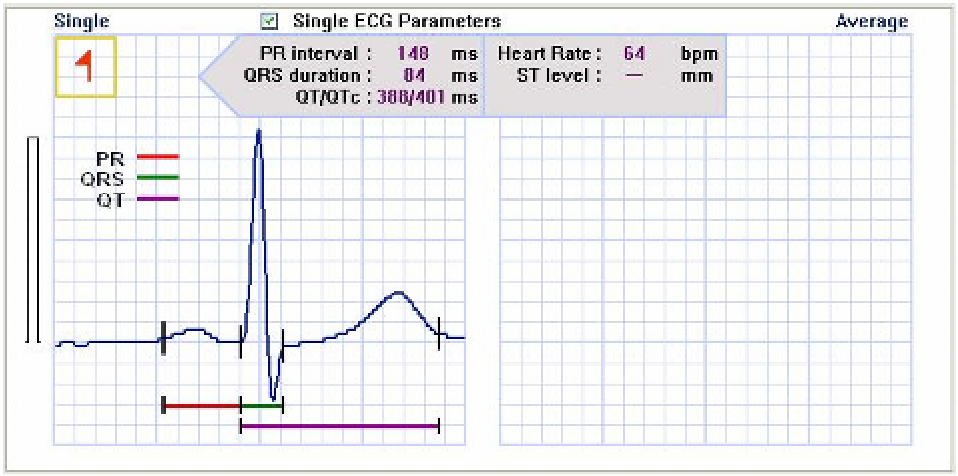


Figure 32. Single ECG Parameters Display

Steps to redefine ECG waves:

1. Display either the Single or Average Parameter display as shown in Figure 32.
2. PR, QRS and QT interval will be calculated automatically.
3. The software will automatically recalculate the parameters if you click and move the vertical bars shown in the parameter box. (Figure 32)
4. Deselect the bar by left-clicking on it again.

FREQUENTLY ASKED QUESTIONS

Q1: What is Cardio[24]?

A1: Cardio[24] is a personalized, home care heart monitoring device. The main function of Cardio[24] is to record ECG tracings anywhere and anytime. Using uniquely designed dry electrodes, users only need to place both thumbs on the electrodes, and their ECG will be recorded. The parameters measured will be displayed on the LCD screen. Together with the software, users can transfer data files to PC for the management of data.

Q2: Why does “Noise” appear during measurement?

A2: Cardio[24] measures the electrical activities emitted by the heart. The “Noise” is the interference with the recording of these signals due to poor contact between the thumbs and the electrodes, excessive movement of the body, and other the environment, etc. When using Cardio[24], it is recommended that users take a stable sitting position, with their feet insulated from the ground. Please measure again when “Noise” appears on LCD screen after the device finishes recording. For detailed operating procedure, please refer to P.7 of the User’s Manual.

Q3: What are some of the factors that may affect the measurement by Cardio[24]?

A3: Besides the factors mentioned in Q2, the followings are some of the factors that may also affect measurements:

1. Thumbs may be greasy, which may affect the transmission of signals. Please use clean water or alcohol to clean thumbs.

2. Thumbs may be too dry. DO NOT use cream. Please use external auxiliary electrode cable & sticky electrode pad.

3. Contact pressure between the thumbs and the electrodes may be too strong. Please place the ball of the thumbs on the electrodes gently.

Even when users have followed the regular procedure described in the User’s Manual to operate Cardio[24], the user may still experience a weak signal. Please contact the distributor, retailer, or visit DailyCare BioMedical’s website: www.dcbiomed.com.

Q4:	How do you use the optional auxiliary electrodes?
A4:	The optional auxiliary electrodes are for users who cannot hold Cardio[24] steadily without shaking, or users whose thumbs are too dry. For detailed instructions, please follow the steps described in P.8 of the User's Manual. Please note that the electrode pads are NOT included. Please buy the electrode pads from a medical device store.
Q5:	Can Cardio[24] be stopped or powered off in the middle of the measurement?
A5:	During the 30 seconds measurement, Cardio[24] cannot be stopped or powered off.
Q6:	Will static electricity affect the measurement of Cardio[24]?
A6:	Cardio[24] is CE certified and has passed electromagnetic interference and compatibility tests. Under normal circumstances, static electricity will not affect the operation of Cardio[24].
Q7:	How do you manage ECG signals if multiple people use a single Cardio[24] device?
A7:	Data cannot be managed on the Cardio[24] device directly. If there is more than one user, please use the software provided for data management. For detailed information, please refer to the User's Manual.
Q8:	Why does the temperature of Cardio[24] rise after the batteries are inserted?
A8:	The rise in temperature is caused by the improper direction of the poles of the batteries when inserted. Please remove the batteries quickly and then reinsert the batteries correctly. Please allow the Cardio[24] to drop to a normal operating temperature before making any measurements.
Q9:	Can the parameters measured by Cardio[24] be used for clinical diagnosis?
A9:	The ECG tracings recorded by Cardio[24] is not for clinical diagnostic purposes. It is only to be used for physician's reference, and to be used for personal home care health management.

Q10: Why does the data recorded in the Cardio24 disappear after batteries are replaced?

A10: Data will remain in the memory for approximately 2 minutes only during battery replacement. Thus, please replace batteries as quickly as possible to preserve data.

Q11: Why does the transferred files to PC and the number of times measured on Cardio24 not match?

A11: Cardio24 can store up to 30 data files in its memory only. When the 30 files limit is exceeded, Cardio24's system will automatically clear all the recorded data and start recording from file serial number 1. Please remember to transfer data files to the PC before or when the 30 maximum files are reached. The purpose of this setup is to remind users to regulary transfer ECG data files to the PC for personal health management.

Q12: How do you transfer Cardio24's ECG data files by internet?

A12: User needs to SAVE the data files first using Cardio24's exclusive software before sending the files by e-mail/FTP. For the detailed procedures, please refer to the software instruction manual.

Q13: How do you maintain Cardio24?

A13: When the dry conduction electrodes on Cardio24 are used regularly, grease and dirt may accumulate, which may affect the recording of signal. Please use a clean wiping cloth to remove grease and dirt. Please DO NOT use any cleaning solutions or organic solvents to prevent damaging the device.

Q14: Can Cardio24 use other external power supply?

A14: No. Cardio24 is to be operated by two replaceable 1.5V (AAA) alkaline batteries. Please do not use other external power supply which may be hazardous and may damage the system and the device.

Q15: Can Cardio24 use accessories other than the ones provided in the standard package?

A15: All standard package accessories meet special specifications of medical device regulations. Please DO NOT use any other accessories

other than the ones provided in the standard package to avoid hazards and subsequent damages to the device and to avoid hazards.

Q16: What to do if the parameters measured by Cardio[24] do not correspond with the user's condition?

A16: In case of an emergency physical condition, users should contact emergency services immediately, or go report immediately to the hospital. If the measured parameters do not correspond with user's condition, please make sure all standard operating procedures are followed. If not, please contact a physician for further check up.

Q17: Can any other fingers be used beside the thumbs for measurement of ECG?

A17: Noise signals may be larger if fingers other than the thumbs are used. It is recommended that users choose the optional Auxiliary Electrodes for measurement of ECG.

Q18: Can Cardio[24] be used while the user is standing up, sitting down, or lying down? Will the measurements make any difference?

A18: Different body positions may affect the cardiac signals slightly. However, by following the standard operating procedure closely, Cardio[24] is able to record ECG signals correctly.

Q19: After exercising, can ECG be measured using Cardio[24]? Wiill the measurement be correct?

A19: Yes, ECG can be recorded after exercise. During measurement, please remain in a stable position to avoid noise interference.

Q20: Can Cardio[24] be used during commuting?

A20: During commuting, if user is able to keep a stable position, Cardio[24] can be used to measure ECG. Usage of Cardio[24] is not recommended during the operation of any vehicle.

Q21: Can conducting gel or other fluids be used when using Cardio[24]?

A21: Cardio[24] is designed to be operated without any conducting gel or other fluids. Please do not apply any conducting gel or other fluids to avoid damaging the thumb electrodes and the device.

GLOSSARY

Aorta

The main trunk of the systemic arteries, carrying blood from the left side of the heart to the arteries of all limbs and organs except the lungs.

Arrhythmia

Irregularity in the force or rhythm of the heart beat.

Atrioventricular (AV) Node

A small mass of specialized cardiac muscle fibers, located in the wall of the right atrium of the heart, that receives heartbeat impulses from the sinoatrial node and directs them to the walls of the ventricles.

Bundle of His

A slender bundle of modified cardiac muscle that passes from the atrioventricular node in the right atrium to the right and left ventricles by way of the septum and that maintains the normal sequence of the heartbeat by conducting the wave of excitation from the right atrium to the ventricles called also *atrioventricular bundle, His bundle*.

Electrocardiogram

The curve traced by an electrocardiograph.

Electrocardiograph

An instrument used in the detection of heart abnormalities. It measures electrical potentials on the body surface and generates a record of the electrical currents associated with heart muscle activity.

Heart Rate (HR)

The number of heartbeat per unit time, usually in minutes.

Hypertrophy

A non-tumorous enlargement of an organ or a tissue as a result of an increase in the size rather than number of constituent cells.

Inferior Vena Cava

Large vein formed by the union of the two common iliac veins that receives

blood from the lower limbs and the pelvic and abdominal viscera and empties into the right atrium of the heart.

Left Atrium

Top left chamber of the heart.

Left Ventricle

Bottom left chamber of the heart.

mm

One mm is one small square on the electrocardiograph.

Myocardial Infarction

Formation of an area of tissue that undergo necrosis as a result of obstruction of local blood supply, as by a thrombus or embolus.

P Wave

Atrial Depolarization (contraction). Normal duration is 0.06 - 0.11 second.

Parameters

A distinguishing characteristic or feature.

PR Interval

Atrial and AV node depolarization. Regular duration is 0.12 - 0.20 seconds.

QRS Interval

Ventricular depolarization. Regular duration is no longer than 0.1 second.

QT Interval

Ventricular refractory time. Duration varies according to rate, age and sex.

Right Atrium

Top right chamber of the heart.

Right Ventricle

Bottom right chamber of the heart.

Right/Left Bundle Branch

Either of the parts of the bundle of His passing respectively to the right and left ventricles.

Sinoatrial (SA) Node

A small mass of specialized cardiac muscle fibers located in the posterior wall of the right atrium of the heart that acts as a pacemaker by generating at regular intervals the electric impulses of the heartbeat.

ST Segment

ST segment represents the period from the end of ventricular depolarization to the beginning of ventricular repolarization.

Superior Vena Cava

A large vein formed by the union of the two brachiocephalic veins and the azygos vein that receives blood from the head, neck, upper limbs, and chest, and empties into the right atrium of the heart.

T Wave

Ventricular Repolarization. Usually 0.5mV or less in Lead I, II and III.

REFERENCES

1. American Heart Association www.americanheart.org
2. National Heart, Lung and Blood Institute www.nhlbi.nih.gov
3. ECG Library www.ecglibrary.com
4. eMedicine www.emedicine.com
5. HeartCenterOnline www.heartcenteronline.com

CONTACT INFORMATION

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